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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/412,863	10/05/1999	ALESSANDRO SETTE	18623-014100	1200

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/412,863	SETTE ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *71-89,108-128,147-164,183-202,215-234 and 241-259* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *108,111,113,119,120,122,123,125,126 and 128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 71-89,109,110,112,114-118,121,124,127,147-164,183-202,215-234 and 241-259.

1. Applicant's election of the peptide AIFQSSMTK and composition containing a T helper epitope in the paper received 2/22/2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 71-107,129-265 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the paper received 2/22/2002.

3. Claims 90-107,129-146,165-182,203-214,235-240,260-265 have been cancelled.

4. Applicant's election with traverse of 9mer and peptide fused to a linker in the reply filed on 6/2/2004 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because of the following reasons. Regarding applicants comments about the 9mer election, the different species have differing amino acid sequences. Regarding applicants comments about the linker election, while the peptide in the conjugates is the same, the various attached molecules are chemically distinct. Regarding applicants comments about peptide fused to a linker versus peptide/liposome, the peptide fused to a linker does not contain a liposome and the peptide/liposome does not contain a linker.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 109,110,112,114-118,121,124,127 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/2/2004.

6. Claims 108,111,113,119,120,122,123,125,126,128 are under consideration.

7. Applicants need to update the status of all US applications disclosed in the specification.

8. Drawings have been submitted which fail to comply with 37 CFR 1.84. Please see the enclosed form PTO-948.

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 120,122,126,128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed pharmaceutical composition or vaccine. The specification does not disclose how to use the instant invention for the in vivo treatment of HIV infection in humans. Applicant has not enabled the breadth of the claimed invention in view of the teachings of the specification because the use for the instant invention disclosed in the specification is the in vivo treatment of HIV infection in humans. The state of the art is such that is unpredictable in the absence of appropriate evidence as to how the instant invention could be used for the in vivo treatment of HIV infection in humans.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same. . . .35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the claimed inventions are drawn to a pharmaceutical composition that can be used to treat/prevent HIV infection and a vaccine for HIV. The substantial/real life use for the claimed inventions are preventing and treating HIV infection. There is currently no known vaccine/pharmaceutical composition containing an HIV peptide for treating or preventing HIV (see Smith, abstract). Smith states: "Moreover, despite a huge amount of money directed to basic and clinical science since that time, a vaccine that can prevent infection by HIV remains elusive." (see page 1, second column). Thus, there is no current HIV vaccine. The claimed pharmaceutical composition would function as a vaccine. Thus, the state of the art is that it is highly unpredictable whether any particular HIV derived peptide could used as a vaccine/pharmaceutical composition to treat HIV in humans. As per Wands factor (8), the claimed inventions are used for preventing and treating HCV infection.

Regarding Wands factors 1-3,7 there is no disclosure in the specification of experimental data indicating that the claimed peptide can be used to prevent or treat HIV infection in vivo in humans. Furthermore, Kent et al. disclose that even if a particular HIV peptide could elicit CTL in a immunized human, that a naturally occurring HIV strain which infected said human had the ability to generate peptides which neutralized said CTL (see abstract). Thus, use of a particular peptide for treatment/prevention of HIV infection is an unpredictable field where extensive experimentation and guidance would be required to use the claimed vaccine or pharmaceutical composition in vivo in humans. The specification provides no evidence predictive of whether the claimed invention could be used in vivo in humans to treat/prevent HIV infection. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.).

Undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

11. In the amendment filed 2/14/2003 applicant indicates that peptide AIFQSSMTK has priority to parent application 08/103396.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 108,111,119,120,122 are rejected under 35 U.S.C. 102(a) as being anticipated by Zhang et al.

Zhang et al. teach the peptide AIFQSSMTK (see Table 2) and a composition containing said peptide and a physiologically acceptable diluent/carrier (eg. tissue culture media, see Table 2, legend). The specification, page 56, line 6-8 indicates that the "carrier" can be an aqueous solution. The recitation of an intended use for the claimed composition (eg. vaccine/pharmaceutical composition) carries no patentable weight in this product claim with regards to the application of prior art.

14. Claims 119,120,122,123,125,126,128 are rejected under 35 U.S.C. 102(b) as being anticipated by Walker et al.

The peptide recited in the claimed compositions is considered to be "open" because the claims are drawn to compositions comprising the claimed peptide wherein other peptides can be present (eg. for example claim 123) and wherein said other peptides could be linked to the peptide of claim 108. Walker et al. teach a peptide comprising AIFQSSMTK (see Table 4) and a composition containing said peptide and a physiologically acceptable diluent/carrier (eg. tissue culture media, see Table 4, legend and page 9515, first column, third paragraph). The specification, page 56, line 6-8 indicates that the "carrier" can be an aqueous solution. The recitation of an intended use for the claimed composition (eg. vaccine/pharmaceutical composition) carries no patentable weight in this product claim with regards to the application of prior art. The

peptide taught by Walker et al. also contains a second peptide (eg. it is 25 amino acids long).

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 108,111,113,119,120,122,123,125,126,128 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. in view of Fuerst et al. (WO 91/04051).

Zhang et al. teach the peptide AIFQSSMTK (see Table 2) and a composition containing said peptide and a physiologically acceptable diluent/carrier (eg. tissue culture media, see Table 2, legend). The specification, page 56, line 6-8 indicates that the "carrier" can be an aqueous solution. The recitation of an intended use for the claimed composition (eg. vaccine/pharmaceutical composition) carries no patentable weight in this product claim with regards to the application of prior art. Zhang et al. do not teach that the peptide is fused to a spacer or a composition containing the claimed peptide and another peptide. Fuerst et al. teach mixtures of HIV CTL epitopes derived from different HIV proteins (see page 5, first incomplete paragraph). Fuerst et al. teach that the CTL peptides can contain exogenous amino acids or fatty acid or

hydrophobic moieties wherein any of the aforementioned could function as spacers(see page 6, last paragraph). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Zhang et al. teach the claimed invention except for the peptide is fused to a spacer or a composition containing the claimed peptide and another peptide, whilst Fuerst et al. teach mixtures of HIV CTL epitopes derived from different HIV proteins and that the CTL peptides can contain exogenous amino acids or fatty acid or hydrophobic moieties wherein any of the aforementioned could function as spacers. One of ordinary skill in the art would have been motivated to do the aforementioned because Fuerst teaches that mixtures of HIV CTL epitopes derived from different HIV proteins can be used in assays (see page 5, first incomplete paragraph) and that the CTL peptides can contain exogenous amino acids or fatty acid or hydrophobic moieties wherein said peptides can be used in vivo (see page 6, last paragraph).

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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